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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,535	10/16/2003	Alex Harel	26662	4030
7590 Martin D. Moynihan PRTSI, Inc. P. O. Box 16446 Arlington, VA 22215			EXAMINER LUSTUSKY, SARA	
			ART UNIT 3735	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Sp

Office Action Summary	Application No. 10/686,535	Applicant(s) HAREL ET AL.	
	Examiner Sara Lustusky	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55-73 is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-24, 26-29, 31-33, 36-39, 41 and 43-54 is/are rejected.
- 7) ☒ Claim(s) 14, 25, 30, 34, 35, 40 and 42 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. PCT/IL02/00286.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/18/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 37 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 37 recites "a bandage that is attached to the subject." This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite --a bandage that is adapted to be attached to the subject--.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-13, 15-22, 26-29, 31-33, 36, 38-39, 41 and 43-54** are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (US 5681260 A).

6. Ueda et al. teaches a system for managing an in vivo vehicle in a subject, comprising:

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- a. a magnet (19, 150) being physically associated with the vehicle (as seen in Figure 4, 17, 75);
- b. an extracorporeal magnetic source for producing a magnetic field for being applied to said magnet, said extracorporeal magnetic source being located outside of the subject (as described in lines 34-40 of column 14);
- c. a detector (121) for detecting a magnetic field from said magnet, said detector being located outside of the subject (as described in lines 41-45 of column 13 and in lines 21-23 of column 15); and
- d. a control module (12, 45) for receiving a magnetic field measurement from said detector and for managing the vehicle according to said magnetic field measurement (as seen in Figure 1a, 5 and 7);
- e. wherein application of said magnetic field comprises application of a gradient of said magnetic field (as described in lines 45-61 of column 20);
- f. wherein managing the vehicle includes at least one of maneuvering, rotating, locating, mobilizing, controlling, monitoring and activating at least one vehicle function (as described in lines 59-60 of column 19) (as seen in Figure 75);
- g. wherein said magnet includes an electromagnet, a soft magnet, a hard magnet or a ferromagnetic material (as described in lines 30-36 of column 11 and in lines 41-46 of column 14) and wherein said magnet may be a permanent magnet, comprising at least one material for producing a permanent magnet having permanent magnetization or at least one material being magnetized in a magnetic field;

- h. wherein said permanent magnet is part of an outer surface of the vehicle or an entire exterior surface of the vehicle is said permanent magnet comprising a connecting element for connecting said permanent magnet to the vehicle (as described in lines 57-59 of column 16 and in lines 19-27 of column 16) (as seen in Figures 14 and 25-27);
- i. wherein the vehicle's path inside the body is preplanned in a horizontal and/or vertical direction (as described in claim 1) and is inherently capable of being preplanned according to the anatomical structure of the examined organ or examined area (i.e. by the physician);
- j. wherein the vehicle's path inside the body is controlled at least partially according to information received about a location of the vehicle, wherein the information is received both from the vehicle itself and from an independent monitoring device (i.e. as viewed by the physician) (as described in lines 11-44 of column 10);
- k. wherein one of the imaging systems or diagnostic systems being used to monitor the position of the vehicle inside the body is independent of the vehicle (as described in lines 11-44 of column 10);
- l. further comprising a receiver for receiving at least one of a data input or a command, said receiving being located in the vehicle (as described in lines 52-60 of column 18);
- m. wherein activation of a function of the vehicle is triggered by a timer (as described in lines 52-60 of column 18);
- n. wherein activation of a function of the vehicle is capable of being triggered, per time frame and/or anatomic position, by an element (160) outside the subject or by

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- signals originating from at least one of said extracorporeal magnetic source and said magnetic field from the vehicle (as described in lines 19-25 and 52-60 of column 18);
- o. wherein activation of said function of the vehicle is capable of being triggered by a change of pH (indicative of a change in concentration of an electrolyte) at the area where the vehicle is located (as described in lines 52-60 of column 18);
 - p. wherein the vehicle contains elements that perform histological tests, an element for performing a local surgical procedure (as described claim 20 and in lines 52-60 of column 18);
 - q. wherein a single Hall probe (131) or an array of Hall probes or reed switches measure the vehicle's location inside the subject (as described in claim 14);
 - r. wherein said detector indicates where the vehicle is within the body during the entire procedure and therefore is capable of indicating when the vehicle passes a predetermined location (as described claims 12 and 13);
 - s. wherein said magnet is at least partially composed of a powder of magnetic material (as described in lines 58-65 of column 17);
 - t. wherein said vehicle further comprises one or more of an imaging element, a functioning element, a power source and a transmitting element (as described in lines 19-25 of column 18 and in claim 20);
 - u. wherein said managing is performed by modulating at least one of a strength and a direction of said magnetic field from said magnet (as described in lines 45-61 of column 20);

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- v. wherein said extracorporeal magnetic source may be comprised of a matrix of coils (as described in lines 10-18 of column 28);
- w. wherein said coils in said matrix are capable of being activated and deactivated (as described in lines 57-64 of column 28);
- x. wherein controlling and managing the vehicle includes moving the vehicle (as described in lines 65-67 of column 28);
- y. wherein the data collected from the vehicle is displayed on a TV/computer monitor and therefore it is inherent that the dimensions of the electromagnetic coils must be selected according to a discretization size in order for the information to be compatible with a digital computer;
- z. wherein an indicator is used to indicate when the vehicle passes said predetermined location (LED 154 and CCD 153) (as described in lines 9-51 of column 18);
- aa. wherein said control module modulates said magnetic field by inducing a plurality of changes in said magnetic field with specific characteristics over time and the location of the vehicle is measured over time as the vehicle moves and the change in the magnetic field is sensed (as described in lines 30-41 of column 16);
- bb. wherein inherently the force and directional vectors between said magnet and said extracorporeal magnetic source are used to calculate a location of the vehicles (as described in lines 25-29 of column 17).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 23 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. (US 5681260 A) in view of Wegner et al. (US 6083163 A) and further in view of Willis et al. (US 6950689 B1).

9. Ueda et al. teaches all the limitations of claim 1, wherein the distance of the vehicle inside the body is monitored using information received from the vehicle itself and from a patient monitoring device, as described above. However, Ueda et al. is silent as to the type of additional patient monitoring being used in connection with a separate TV monitor.

10. Wegner et al. teaches a patient monitoring device designed for real-time use in combination with a surgical procedure, wherein the monitoring device is used for position guidance (as described in the abstract), wherein distance of the object or area being monitored is determined according to the Doppler principal (as described in lines 42-64 of column 2). While Wegner et al. teaches the use of sound to count the distance of the object by applying the Doppler principal, Wegner et al. is silent as to the type of device used to count the distance.

11. Willis et al. teaches that at the time of the invention it was commonly known in the art that devices using sound to detect objects, generate images and to calculate distances use distance counters to calculate the distance to an object after a signal has been transmitted (as described in the abstract and in lines 5-15 of column 17).

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12. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a position guidance system similar to that of Wegner et al. as part of a system to perform a surgical procedure to guide a vehicle in vivo similar to that of Ueda et al. in order to overcome the shortcomings of visual systems such as size constraint or available positioning of the detector portion (i.e. a camera on an endoscope vs. ultrasound). It would have been further inherently obvious to one of ordinary skill in the art at the time of the invention that the device of Wegner et al. would include a distance counter in order to calculate the distance of the object using sound by applying the Doppler principal in view of the teachings of Willis et al.

Allowable Subject Matter

13. **Claims 14, 25, 30, 34-35, 37, 40, and 42** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 55-73 are allowable over the prior art of record.

15. The following is a statement of reasons for the indication of allowable subject matter:

16. Regarding claim 14, none of the prior art of record teaches or fairly suggests a system for managing an in vivo vehicle in a subject comprising a magnet physically associated with the vehicle, an extracorporeal magnetic source for applying a magnetic field to the magnet, a detector for detecting a magnetic field from said magnet, a control module for receiving information from the detector and for managing the vehicle according to the information, wherein the system comprises a connecting element for connecting a permanent magnet to the vehicle, wherein said connecting element is used as an antenna to send and receive signals to and from the vehicle.

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17. Regarding claim 25, none of the prior art of record teaches or fairly suggests a system for managing an in vivo vehicle in a subject comprising a magnet physically associated with the vehicle, an extracorporeal magnetic source for applying a magnetic field to the magnet, a detector for detecting a magnetic field from said magnet, a control module for receiving information from the detector and for managing the vehicle according to the information, wherein distance is measured by a laser Doppler.

18. Regarding claim 30, none of the prior art of record teaches or fairly suggests a system for managing an in vivo vehicle in a subject comprising a magnet physically associated with the vehicle, an extracorporeal magnetic source for applying a magnetic field to the magnet, a detector for detecting a magnetic field from said magnet, a control module for receiving information from the detector and for managing the vehicle according to the information, wherein activation of a function of the vehicle is triggered by a change of pressure on the vehicle.

19. Regarding claims 34-35, none of the prior art of record teaches or fairly suggests a system for managing an in vivo vehicle in a subject comprising a magnet physically associated with the vehicle, an extracorporeal magnetic source for applying a magnetic field to the magnet, a detector for detecting a magnetic field from said magnet, a control module for receiving information from the detector and for managing the vehicle according to the information, wherein a pressure is applied by or on the vehicle and is measured by a pressure-measuring element, wherein said pressure indicates a change in magnetic force and is used to calculate an inclination angle of the vehicle.

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20. Regarding claim 37, none of the prior art of record teaches or fairly suggests a system for managing an in vivo vehicle in a subject comprising a magnet physically associated with the vehicle, an extracorporeal magnetic source for applying a magnetic field to the magnet, a detector for detecting a magnetic field from said magnet, a control module for receiving information from the detector and for managing the vehicle according to the information, wherein said detector and said extracorporeal magnetic source are assembled on a bandage that is attached to the subject.

21. Regarding claim 40, none of the prior art of record teaches or fairly suggests a system for managing an in vivo vehicle in a subject comprising a magnet physically associated with the vehicle, an extracorporeal magnetic source for applying a magnetic field to the magnet, a detector for detecting a magnetic field from said magnet, a control module for receiving information from the detector and for managing the vehicle according to the information, wherein said detector comprises an array of reed switches used to indicate when the vehicle passes a predetermined location.

22. Regarding claim 42, none of the prior art of record teaches or fairly suggests a system for managing an in vivo vehicle in a subject comprising a magnet physically associated with the vehicle, an extracorporeal magnetic source for applying a magnetic field to the magnet, a detector for detecting a magnetic field from said magnet, a control module for receiving information from the detector and for managing the vehicle according to the information, wherein said detector comprises a electromagnetic, electronic, optical or mechanical flip switch used to indicate when the vehicle passes a predetermined location

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23. Regarding claims 55-73, none of the prior art of record teaches or fairly suggests a system for managing an in vivo vehicle in a subject comprising a magnet physically associated with the vehicle, an extracorporeal magnetic source for applying a magnetic field to the magnet, a detector for detecting a magnetic field from said magnet, a control module for receiving information from the detector and for managing the vehicle according to the information, wherein the extracorporeal magnetic source is comprised of a matrix of annular permanent magnets arranged on a grid.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McDougall et al. (US 4689591 A) teaches various magnetic arrangements for an MRI apparatus. Gazdzinski (US 2001/0051766 A1) teaches a maneuverable vehicle for exploring the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

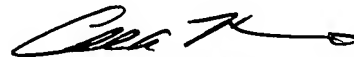
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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S.L.



CHARLES A. MARMOR II
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700